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Dr. Stephen Sundlof Director, FDA, Center for Veterinary Medicine 7500 Standish Place Room 482 Rockville, MD 20855

Dear Dr. Sundlof:

The Federation of Animal Science Societies (FASS) Committee on Food Safety, Animal Drugs and Animal Health has reviewed the Citizen's Petition, Docket Number 99P-0485, filed on March 11, 1999 by the Center for Science in the Public Interest, and entitled "Petition to Rescind Approvals of the Subtherapeutic Uses in Livestock of Antibiotics Used in (or Related to Those Used in) Human Medicine." On behalf of the FASS, enclosed please find our response, entitled "The Correct Perspective on the Use of Antibiotics in Animals", to Docket Number 99P-0485. Should you require any additional information, please contact me (gcromwel@ca.uky.edu).

Sincerely,

Gary L. Cromwell

Say Conwell

Chair

FASS Committee on Food Safety, Animal Drugs, and Animal Health

Enclosure

cc. Dockets Management Branch Food and Drug Administration Room 1061 5630 Fishers Lane Rockville, MD 20852

Federation of Animal Science Societies Comments in Response to Docket # 98P-0485

Committee on Food Safety, Animal Drugs, and Animal Health Federation of Animal Science Societies

THE CORRECT PERSPECTIVE ON THE USE OF ANTIBIOTICS IN ANIMALS A Reasoned Response to the Citizens Petition, Center for Science in the Public Interest

Antibiotic resistance in bacteria was present prior to the discovery (1939) and introduction (1946) of penicillin (1). Penicillin has been in existence since the first mold appeared on bread. Most present day antibiotics have been isolated from microorganisms present in the soil. The point is, antibiotics have been present in the environment long before their discovery by man. Therefore, antibiotic resistance in microorganisms has been at work long before the discovery of the R-factor phenomenon (resistance) in 1960.

Antibiotic resistance is of concern to human and animal practitioners. Reducing unnecessary use of antibiotics in hospitals, doctor's offices and on farms, in this order, is a prudent step to reduce the potential for antibiotic resistance. Nearly 60 % of all antibiotics used in the U.S. is used in humans. Most of the remainder is used in animals, including dogs and cats.

Many illnesses in humans are caused by foodborne pathogens. These pathogens have been present in food long before antibiotics were discovered. Therefore, it is incorrect to imply that foodborne illnesses are the result of antibiotic resistance. To reduce the risk of foodborne pathogens, proper handling (refrigeration) and cooking are the first priority.

It is <u>speculated</u> that agricultural uses of antibiotics "cause" the development of antibiotic resistance in human pathogens and <u>may</u> jeopardize their effectiveness in treating human or animal diseases. Logic would say if there has been an increase in the resistance of human pathogens, since nearly 60 % of all antibiotics are used directly in humans, this use must be the primary reason for any increase in the resistance of pathogens in humans. This is the exact conclusion reached by physician/microbiologists working in hospitals (2, 3, 4). One concluded (4):

"The perception of increasing antibiotic resistance appears to be related to the large number of papers dealing with the subject rather than statistical evidence that resistance is increasing. An attempt to ban the use of antibiotics in animal feed based on increased bacterial resistance in patients is an attempt to solve a problem that fortunately does not exist."

Recently (1999), the Institute of Medicine, National Research Council (IOM-NRC) completed a study entitled "The Use of Drugs in Food Animals-Benefits and Risks", with major emphasis on antibiotics (IOM-NRC, 5). Statements taken from their extensive study and publication (253 pages) are as follows:

"Use of antibiotics increases the risk of emergence of microorganisms that are resistant to specific, and perhaps other, antibiotics. Development of this kind of resistance is not restricted to antibiotic use in food animals; it is far more prevalent because of misuses in human medicine." (p7)

- "...the development of hospital-acquired vancomycin resistance in pathogens is a major human health concern largely devoid of input from agricultural sources in the United States." (p22)
- "...it is unclear that the observed or perceived increases in transference of antibiotic resistance to humans are associated with the use of antibiotics in the food-animal industry." (p8) This is similar to a 1989 Institute of Medicine report (6) and other study committees.

"Given some limited facts, authoritative opinions, and some projections on possiblealthough not necessarily probable-biological events, scenarios can be quickly woven to paint a bleak picture of the future." (p22)

Sub-therapeutic use of antibiotics in food-producing animals promotes the health of these animals and therefore should not compromise the health of the human population (IOM-NRC, p viii). "When antibiotics stabilize animal health, food animals are able to use nutrients for growth and production rather than to fight infection" (IOM-NRC, p4). This leads to the improvement in growth and feed efficiency when sub-therapeutic levels of antibiotics are used in food producing animals. Additionally, mortality and morbidity are decreased. Because of these benefits, sub-therapeutic use of antibiotics improves the economic return to the food animal producer, and thereby decreases the cost of animal food products to the consumer. "...the economics of food-animal production depended on antibiotic and anti-microbial drug use in common animal production practices that facilitated the affordable, plentiful supply of meat and eggs, providing the quality, nutrition, and safety that consumers desired" (IOM-NRC, p21).

We believe that the correct perspective on the use of antibiotics in animals was stated by the 1999 IOM-NRC committee:

"The committee concludes that the use of drugs in the food-animal production industry is not without some problems and concerns, but does not appear to constitute an immediate public health concern" (p9). They did "recommend establishment of integrated national data-bases to support a rational, visible, science-driven decision-making process and policy development for regulatory approval and use of antibiotics in food animals, which would ensure the effectiveness of these drugs and the safety of foods of animal origin" (p11)

Submitted by the Federation of Animal Science Societies 1111 North Dunlap Ave. Savoy, IL 61874

References:

- 1. Preston, R.L. 1987. The role of animal drugs in food animal production. In: Symposium on Animal Drug Use-Dollars and Sense. Center for Veterinary Medicine, Food and Drug Administration, Rockville, MD.
- 2. Kampelmacher, E.H. 1969. Foods of animal origin as a vehicle for transmission of drug-resistant organisms to animals and man. In: Proc. Symp. on The Use of Drugs in Animal Feeds. pp318-326. Natl. Acad. Sci., Washington, D.C.
- 3. Finland, M. 1969. Discussion: Effects of Drug resistant organisms on the ecology of serious infections within hospitals. Ibid, pp346-349.
- 4. Lorian, V. 1986. Antibiotic sensitivity patterns of human pathogens in American hospitals. J. Anim. Sci. 62 (Suppl. 3): 49-55.
- 5. Inst. of Med.-Natl. Res. Council, 1999. The Use of Drugs in Food Animals-Benefits and Risks. Natl. Acad. Press, Washington, D.C.
- 6. Inst. of Med. 1989. Human health risks with the subtherapeutic use of penicillin or tetracyclines in animal feed. Natl. Acad. Press., Washington, D.C.

